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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gerald D. Cagle

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EXAMINER

ARIANI, KADE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/705,441	Applicant(s) CAGLE ET AL.	
	Examiner KADE ARIANI	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on October 29, 2008, has been received and entered.

New Claim 78 has been added.

Claims 73-78 are pending in this application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 74 and 76 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn due to Applicant's amendments to the claims filed on 10/29/2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamien M. (Aust. Fam. Physician. 1999, Vol. 28, No. 8, p.817 and 828) in view of Asgharian et al. (US Patent No. 6,139,646), and further in view of Hunt et al. (US 5,897,833 A), and further in view of Rothberg, S. (Science 1967, Vol. 156, p.90-93).

Claims 73-78 are drawn to a composition for assisting in the removal of human cerumen from the external ear canal, the composition comprising about 0.5% to about 15% w/v sodium bicarbonate, about 50 AU/ml to about 500 AU/ml methyl trypsin, about 1% to about 20% w/v glycerin (about 7% w/v glycerin), about 0.001% to about 0.1% w/v benzalkonium chloride (0.01% w/v benzalkonium chloride), and water, said composition having a pH about 7.5 to about 9.0, wherein the composition is configured for, upon location within the ear canal, digesting human cerumen located within the ear canal, the composition further comprising about 0.1% to about 8% sodium citrate.2H₂O (about 3% sodium citrate.2H₂O) and about 0.05% to about 1% w/v nonionic surfactant selected from poly(oxyethylene)–poly(oxypropylene) block copolymers (about 0.25% w/v), said composition having a pH about 8.0 to about 8.3, wherein the combination of methyl trypsin and sodium bicarbonate exhibit synergy in digesting cerumen.

Kamien teaches a composition for assisting in the removal of human cerumen from the external ear canal comprising 15% sodium bicarbonate solution, and further teaches a solution of 15% sodium bicarbonate is the cheapest and most effective cerumenolytic (p.817 1st column 1st paragraph lines 17-18 and p.828 2nd column 2nd paragraph).

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Kamien does not teach methyl trypsin, glycerin, benzalkonium chloride, sodium citrate.2H₂O, a nonionic surfactant, in the claimed w/v percentages, and the composition having a pH about 7.5 to about 9.0 (about 8.0 to about 8.3).

However, Asgharian et al. teach a multipurpose liquid enzyme and disinfecting composition comprising methyl trypsin in amounts of 1-100 PAU/ml (or 1 -100 AU/ml) (column 9, lines 13-14), 25% glycerin (glycerol) (Example 3, ingredients, line 40), sodium citrate dehydrate (col.4 line 23-43). Asgharian et al. also teach the enzyme composition is a multi-purpose composition (column 8 lines 56) and that the disinfecting solution may contain various components in addition to the enzyme, sodium citrate, 0.05% poloxamine 1304 (Tetronic ®1304) (column 11 lines 57 and 59 and column 16 Example 6, Table, line 12), benzalkonium halides (column 10 lines 37). Asgharian et al. also teach sodium bicarbonate in an amount of at least 0.2% (Example 4).

Further motivation to modify the composition of Kamien is in Hunt et al. who teach a composition comprising an enzyme effective to remove debris or deposit (protein-based debris), the enzyme is trypsin, an effective amount of a preservative component in the liquid medium, the useful preservative component is benzalkonium chloride (column 6 lines 51-52). It must be noted that at the time the invention was made it was well known in the art that cerumen plugs were consist of large amount of keratin debris (up to 60%) and trypsin solubilized keratin (see Rothberg, S.) Hunt et al. also teach the activity of the enzyme activity is pH dependent. Moreover, at the time the invention was made it was well known in the art that the optimum pH of trypsin is about

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8.0. Thus, a person of ordinary skill in the art would have realized to provide a composition of trypsin at a pH of about 8.0 to about 8.3 for optimal enzyme activity.

Therefore, in view of the above teachings, a person of ordinary skill in the art at the time the invention was made could have been motivated to modify the cerumenolytic composition as taught by Kamien by adding a preservative composition comprising methyl trypsin according to the teachings of Asgharian et al. and Hunt et al. in order to provide an improved cerumenolytic composition with predictable and additive result of digesting cerumen, because the art clearly teaches the keratinous nature of the cerumen plugs, trypsin's ability to solubilize keratin, and the effective cerumenolytic activity of 15% sodium bicarbonate solution.

Response to Arguments

Applicant's arguments filed on 10/29/2008 have been fully considered but they are not persuasive.

Applicant argues that Asgharian et al. is directed to contact lens disinfection compositions and there is no indication in the prior art that such compositions would be desirable for the removal of human cerumen from an individual ear canal. However, the examiner has not alleged that Asgharian speaks directly to the treatment of cerumen but has applied Asgharian in the rejection to show a composition of trypsin with the other claimed components. The examiners rejection is based on the fact that the prior art clearly recognizes that cerumen is keratin based and that trypsin is known to

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hydrolyze keratin and as such would have been an obvious choice to treat cerumen. Therefore, it also follows that it would be obvious to include the other claimed components in a trypsin composition because Asgharian teaches their well known effects on and compatibility with the enzyme/enzyme solution. It also would be obvious to include the trypsin in a composition with sodium bicarbonate because the prior art clearly teaches that sodium bicarbonate is a cerumenolytic.

Applicant argues that the amount of sodium bicarbonate suggested in Asgharian et al. are too low to effectively digest appreciable amounts of human cerumen, and because of the low amount of sodium bicarbonate employed in Asgharian et al. it is unlikely that the skilled artisan would use the teachings of Asgharian et al. in forming a composition for digesting human cerumen.

However, as mentioned immediately above, Kamien teaches a solution of 15% sodium bicarbonate is the cheapest and most effective cerumenolytic solution.

The claimed composition would have been obvious because, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at ___, 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

“[I]t can be important to identify a reason that would have prompted a person of ordinary

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skill in the relevant field to combine the elements in the way the claimed new invention does.” KSR, 550 U.S. at ___, 82 USPQ2d at 1396.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651